3, line 27, through page 4, line 28, original claim 10, and page 13, line 19, through page 14, line 8. No new matter enters by these amendments.

The abstract has been amended, as required by the Office.

Initially, at page 2 of Paper No. 3, the Office discusses the claim for priority under 35 U.S.C. §§ 119 and 120. Applicants note that the related prior application Serial No. 06/771,230, filed August 30, 1985, contains the same claims as this application. The question of proper support may arise when new claims are added or a claim amended. (See M.P.E.P. § 2163.03.) However, in this case, at least prior to this response, no claims had been added or amended. Thus, the support for claims 15-17 is adequately disclosed in at least the original claims. While claims 15-17 have been canceled, the facts show that the proper support for these claims does exist in the related prior application.

In addition, applicants enclose a copy of the certified priority application, GB 84 23659, filed September 19, 1984. That document was filed in related application Serial No. 06/771,230 on March 26, 1986.

The specification is objected to and claims 15-17 stand rejected under 35 U.S.C. § 112, first paragraph, as the disclosure is allegedly not commensurate with the scope of the claims. Applicants respectfully traverse this rejection.

Solely to advance the prosecution of this case, claims 15-17 have been canceled. New claims 23-29 have been added. Each of the DNA fragments recited in claims 23-27 are literally disclosed in the specification. The restriction sites listed on page 4 of the

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specification indicates that applicants possessed each DNA fragment of HIV-1 that can be generated with at least the restriction enzymes noted. One skilled in the art would clearly recognize that applicants possessed at least the presently claimed DNA fragments from the disclosure. Furthermore, as only routine techniques would have produced and made useful any of the DNA fragments indicated in the list on page 4 of the specification, the disclosure clearly enables claims directed to those DNA fragments. Since dependent claims 28 and 29 merely recite the DNA fragments in vectors or transformed hosts, both aspects of the invention within applicants' original disclosure (see, for example, page 13, line 19, through page 14, line 8) and within the ordinary skilled artisan's ability at the time of filing, claims 23 and 24 are also adequately disclosed and enabled. Thus, applicants' specification satisfies 35 U.S.C. § 112, first paragraph, for new claims 23-29.

At page 4 of Paper No. 3, the Office asserts that applicants' specification "only teaches the isolation of the cloned LAV DNAs consisting of pLAV75, pLAV82, pLAV13, λJ19, and λJ81." On the contrary, the isolation and characterization of those plasmids and phages are specifically exemplified. Nowhere do the applicants state that their invention is limited to only the specifically exemplified plasmids and phages. No reason exists to limit applicants' invention to only the exemplified species. Furthermore, there is no reason stated in Paper No. 3 that would lead one to doubt that the applicants did indeed possess the presently claimed invention or doubt that the presently claimed invention was enabled by their disclosure at the time of filing.

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In light of the above, the objection and rejection are now moot or should not apply to new claims 23-29.

The specification is objected to and claims 15-17 stand rejected under 35 U.S.C. § 112, first paragraph, as allegedly failing to provide an adequate written description of the invention. Applicants respectfully traverse this rejection.

As noted above, claims 15-17 have been canceled solely to advance prosecution. Applicants have also noted above that claims 15-17 were originally claimed in applicants' related prior application Serial No. 06/771,230, filed August 30, 1985. Thus, claims 15-17 have literal support in the original claims.

The proper descriptive support for new claims 23-29, as shown above, is also found in applicants' specification. Therefore, this rejection is in error, is now moot, and does not apply to new claims 23-29.

Claims 1, 2, 5-7, 9-12, and 15-17 stand rejected under 35 U.S.C. § 112, second paragraph, as allegedly being vague and indefinite and for allegedly failing to particularly point out and distinctly claim the subject matter which applicants regard as the invention. Applicants respectfully traverse this rejection.

All of the claims so rejected have been canceled solely to advance prosecution in this case. New claims 23-29 have been added. The Office points to various recitations in the rejected claims that allegedly provide a basis for this rejection. (Pages 5 and 6 of Paper No. 3.) However, new claims 23-29 do not recite "cloned DNA" or any parenthetical terms.

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While new claims 23-29 do recite "approximately," these claims are definite and would be understood by one skilled in the art, as will be shown below.

The new claims 23-29 identify the claimed DNA fragments by specifically referring to a restriction site and the approximate location of that site in the HIV-1 sequence disclosed in the specification. That one skilled in the art understands the metes and bounds of an identified restriction fragment cannot be legitimately disputed. After all, restriction fragments were well known years before applicants' filing date. Applicants include the term "approximately" in order to identify the particular restriction sites corresponding to the claimed DNA fragments. As noted in the specification at page 3, line 32, through page 4, line 2, the coordinates of the restrictions sites are estimated. However, there is no dispute that these sites do actually exist. In order to identify which of the Bam HI or Bgl II sites is involved, for example, applicants include the approximate coordinate of the restriction site. Therefore, not only is the recited term "approximately" not vague or indefinite, it actually helps one skilled in the art identify the claimed DNA fragment.

If the Office applies this rejection to new claims 23-29, applicants respectfully submit that the above comments show that 35 U.S.C. § 112, second paragraph, has been satisfied.

Claims 1, 2, 5-7, and 9-12 stand rejected under 35 U.S.C. § 102(a) as allegedly anticipated by or, in the alternative, under 35 U.S.C. § 103 as allegedly being unpatentable over Arya *et al.* (Arya), Science 225:927-930 (1984). Applicants respectfully traverse both of these rejections.

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The rejected claims have been canceled solely to advance prosecution of this case. The comments below show, however, that the rejection to the canceled claims was in error and that new claims 23-29 should not be so rejected.

In order to anticipate, Arya must be an enabling disclosure of each and every element of the presently claimed invention. Hybritech Inc. v. Monoclonal Antibodies, Inc., 231 U.S.P.Q. 81, 90 (Fed. Cir. 1986); In re Epstein, 31 U.S.P.Q.2d 1817, 1823 (Fed. Cir. 1994). As noted in Paper No. 3 at page 8, Arya does not "recite the specific restriction sites of the instant invention...." Since the restriction sites identifying the claimed DNA fragments are an element of the claimed invention and Arya nowhere discloses the restriction sites, Arya cannot anticipate present claims 23-29.

In order for Arya to inherently disclose the presently claimed invention, as asserted in Paper No. 3 at page 8, each and every element of the claimed invention must "flow undeniably from the express disclosure" of Arya. *See* Hughes Aircraft Co. v. U.S., 8 U.S.P.Q.2d 1580, 1583 (Ct. Cl. 1988). As developed more fully below in the response to the § 103 rejection, Arya merely discusses "cDNA preparations." The Office asserts, apparently, that the missing restrictions sites, noted above, are inherently disclosed by the "cDNA preparations" of Arya. However, no evidence is provided to substantiate that assertion.

For the purposes of this rejection under 35 U.S.C. § 102(a), the actual contents of the "cDNA preparations" are as unknown now as they were when Arya *et al.* made them. The Office provides no evidence that even suggests that the actual contents of the "cDNA

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preparations" of Arya can actually and "undeniably" be the presently claimed invention. Without such evidence, Arya cannot inherently disclose or anticipate the claimed invention.

In fact, there is no evidence of what the sequences contained in the "cDNA preparations" of Arya are. That they allegedly hybridize to RNA of HTLV-I and HTLV-II derived sequences is just as likely a showing that the "cDNA preparations" are contaminated with HTLV-I and HTLV-II sequences as anything allegedly suggested by Arya. The facts remain that, from the four corners of Arya, there is no way to determine the "undeniable" contents of the "cDNA preparations." Without such a showing, a *prima facie* case of anticipation cannot be made.

For these reasons, at least, claims 18-24 cannot be considered anticipated by Arya.

The proposition that a desire to reach a certain result cannot render the result itself obvious has been expressed in the patent cases as "obvious to try." *See, for example,* Amgen, Inc. v. Chugai Pharmaceutical Co., 18 U.S.P.Q.2d 1016, 1022 (Fed. Cir. 1991). Those same cases hold that "obvious to try" is not the appropriate standard under 35 U.S.C. § 103. *Id.* In this case, at best, the § 103 rejection based on the procedure discussed in Arya is nothing more than a rejection based on the improper "obvious to try" standard in order to arrive at applicants' claimed invention. Furthermore, in this case, an actual DNA fragment or molecule cannot be considered unpatentable over an allegedly obvious method to produce the DNA fragment. In re Deuel, 34 U.S.P.Q.2d 1210, 1215 (Fed. Cir. 1995). Thus, as will be shown below, the presently claimed invention is not obvious over Arya.

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There can be no dispute that Arya does not in any way identify, characterize, or provide to one skilled in the art a cloned sequence of any HIV-1 isolate. The only relevant information Arya provides, as noted above and in Paper No. 3 at page 8, is "cDNA preparations" from cells that are allegedly infected with sera from AIDS patients allegedly containing HTLV-III_B and HTLV-III_Z isolates. (See the text of Arya at page 928, first full paragraph.) Whether or not these "cDNA preparations" contain any sequences from an HIV-1 virus was certainly not known to Arya *et al.* and could not possibly have been known to one skilled in the art from the four corners of what Arya discusses.

That Arya *et al.* desired to produce a HIV-1 clone is likely. Many groups also desired to produce such a clone. That one skilled in the art might consider the procedure discussed in Arya as one that can theoretically produce a cDNA clone of an HIV-1 isolate is possible. However, as evidenced by the disclosure in this and prior applications, the applicants actually did isolate, characterize, and provide for one skilled in the art HIV-1 cloned DNA. The difference between applicants' disclosure of clones, biological deposits, and restriction maps and that alleged of Arya extinguishes any possibility that Arya *et al.* had accomplished their goal of cloning HIV-1. All that the discussion and results of Arya could possibly suggest is that their "cDNA preparations" might theoretically contain a cDNA clone of HIV-1. The discussion and results cannot render obvious an actual clone.

As the Federal Circuit stated recently in In re Deuel, 34 U.S.P.Q.2d 1210, 1215 (Fed. Cir. 1995):

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> We affirm today the principle, stated in *Bell*, that the existence of a general method of isolating cDNA or DNA molecules is essentially irrelevant to the question whether the specific molecules themselves would have been obvious, in the absence of other prior art that suggests the claimed DNAs.

Here, applicants claim specific DNA fragments having a sequence between disclosed restriction sites on the disclosed HIV-1 genome. Arya, on the other hand, neither provides any evidence of the existence of the claimed DNA fragments nor any suggestion of HIV-1 DNAs. Understanding that Arya suggests, at most, that it would be "obvious to try" producing the claimed DNA fragments, and following the clear statement from the Federal Circuit leads to the inevitable conclusion that Arya cannot render obvious applicants' claimed invention.

The Office asserts that it is applicants' burden to show an unobvious distinction between the alleged material in the "prior art" (Arya) and the claimed DNAs. (Paper No. 3 at pages 8-9.) However, the alleged "material" of Arya could have just as likely been a contaminant from the known HTLV-I and HTLV-II nucleic acids present during the work of Arya *et al.* Here, there is no evidence to possibly teach or suggest what the actual "material" discussed in Arya really is. In these circumstances, it is improper for the Office to attempt to shift the burden to applicants to explain what it is.

For these reasons, at least, claims 23-29 cannot be considered obvious over Arya.

Claims 1, 2, 5-7, and 9-12 stand rejected under 35 U.S.C. § 102(e) as allegedly anticipated by, or, in the alternative, under 35 U.S.C. § 103 as allegedly unpatentable over Levy (U.S. Patent 4,716,102). Applicants respectfully traverse this rejection.

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The rejected claims have been canceled solely to advance prosecution of this case. The comments below show, however, that the rejection to the canceled claims was in error and that new claims 23-29 should not be so rejected.

Levy discusses a virus. Levy includes prophetic examples discussing "DNA Derived from ARV" and "Hybridization Assays Using Labeled DNA Derived from ARV" beginning at column 4, line 25. However, as is clear from the actual text of Levy, no DNA from ARV was ever derived. Neither was any hybridization assay performed. Thus, Levy discusses none of the elements of applicants' claimed invention. Accordingly, there can be no anticipation under 35 U.S.C. § 102(e).

Similar to the situation with Arya, Levy merely presents prophetic examples encompassing a method that, when tried, might potentially yield DNA derived from ARV. At most, it might be "obvious to try" the procedure Levy discusses, but Levy cannot render obvious the claimed DNA fragments. Furthermore, the decision and statements from In re Deuel, discussed above, apply equally to this rejection over Levy as they do to the rejection over Arya.

For this reason, at least, claims 23-29 cannot be considered obvious over Levy.

Claims 15-17 stand rejected under 35 U.S.C. § 102(b) as allegedly anticipated by or, in the alternative, under 35 U.S.C. § 103 as allegedly unpatentable over Wain-Hobson *et al.* Applicants respectfully traverse both of these rejections.

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The rejected claims have been canceled solely to advance prosecution of this case. The comments below show, however, that the rejection to the canceled claims was in error and that new claims 23-29 should not be so rejected.

Applicants have shown above that claims 15-17 are properly supported by applicants' original specification. The applicants' priority application, GB 84 23659, filed September 19, 1984, antedates the publication of Wain-Hobson. The disclosure of GB 84 23659 is virtually identical to the original specification in this application. Therefore, having met the requirements of 35 U.S.C. § 119, applicants are entitled to the September 19, 1984 filing date of GB 84 23659 and Wain-Hobson *et al.* is not "prior art" to this application.

For this reason, both of the above rejections to canceled claims 15-17 are in error and new claims 23-29 should not be considered anticipated or obvious over Wain-Hobson.

In view of the above comments, applicants respectfully request that a Notice of Allowance be issued for claims 23-29.

If there are any fees due in connection with the filing of this response, please charge such fees to our Deposit Account No. 06-0916. If an extension of time is required under 37

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C.F.R. § 1.36 and not accounted for above, such an extension is respectfully requested and the fee should be charged to Deposit Account No. 06-0916.

Respectfully Submitted,

FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER, L.L.P.

Date: March 28, 1996

David J. Kulik
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Enclosure: copy of GB 84 23659, as filed in Serial No. 06/771,230 on March 26, 1986

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